

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
November 9, 2012

DRAFT AGENDA

The committee will discuss data submitted by MSD Consumer Care, Inc. to support new drug application (NDA) 202211, for the partial switch from prescription to over-the-counter (OTC) of the oxybutynin transdermal system (proposed trade name OXYTROL FOR WOMEN). The proposed OTC use is "treats overactive bladder in women." The data to be discussed will include a summary of the postmarketing experience with the oxybutynin transdermal system, and the results of consumer studies, including label comprehension studies, self-selection studies, and an actual use study. The committee will be asked to consider whether the data support the appropriate and safe use of oxybutynin transdermal system by OTC consumers.

8:00 a.m.	Call to Order and Introduction of Committee	Marcus Reidenberg, MD, FACP Acting Chair, NDAC
8:05 a.m.	Conflict of Interest Statement	Minh Doan, PharmD Acting Designated Federal Officer, NDAC
8:10 a.m.	NDAC Member Appreciation and FDA Introductory Remarks	Andrea Leonard-Segal, MD Director Division of Nonprescription Clinical Evaluation (DNCE) Office of Drug Evaluation IV (ODE IV) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	SPONSOR PRESENTATIONS	
	Introduction	Edwin Hemwall, PhD R&D Leader, Rx-to-OTC Switch Merck Consumer Care
	Clinical Overview of Oxytrol	Rajesh Mishra, MD, PhD Head, Medical Affairs Merck Consumer Care
	Label Comprehension and Self-Selection Studies	Stephen Neumann, MA Head, Consumer Research Merck Consumer Care
	Actual Use Study: CONTROL	Amy Replogle, MS Program Leader, Rx-to-OTC Switch Merck Consumer Care
	Oxytrol for OAB in an OTC Setting	Eman Elkadry, MD Harvard Medical School Fellowship Director and Attending Physician Mount Auburn Hospital, Cambridge, MA

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DRAFT AGENDA (cont.)

SPONSOR PRESENTATIONS (CONT.)

Consumer Education & Support

Kristie Licata, MBA
Product Development Leader, Rx-to-OTC
Switch
Merck Consumer Care

Summary

Edwin Hemwall, PhD

9:40 a.m. Clarifying Questions

10:05 a.m. **BREAK**

10:20 a.m. **FDA PRESENTATIONS**

Overview of the Efficacy and Safety
Database for NDA 21-351

Donald McNellis, MD
Medical Officer
Division of Reproductive and Urological Products
Office of Drug Evaluation III (ODE III)
OND, CDER, FDA

Oxytrol for Women ®
Label Comprehension and
Self Selection Consumer Research

Barbara Cohen, MPA
Social Science Analyst
DNCE, ODE IV, OND, CDER, FDA

Oxytrol for Women® –
The Clinical Perspective

Ryan Raffaelli, MD
Medical Reviewer
DNCE, ODE IV, OND, CDER, FDA

11:35 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**